IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Wang et al.
Appl. No.:	10/598,909
Conf. No.:	1906
Filed:	September 14, 2006
Title:	DELIVERY OF FUNCTIONAL INGREDIENTS
Art Unit:	1655
Examiner:	Q. Mi
Docket No.:	0112701-00753

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:

Chemist; Chemical Engineer; Processing; Extraction.

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated April 7, 2009 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the references cited therein, U.S. Patent No. 6,264,982 to Pruthi et al. ("*Pruthi*") as evidenced by Polyphenolic constitutents of the flowers of Berberis aristata, Journal of the Indian chemical society, 68 (9): 531-532, 19991 to Sivakumar et al. ("*Sivakumar*") and

Occurrence of carotenoids in fruits of the genus Berberis, Bulletin De L'Academie Polonoise Des Sciences, 13 (5):251-255, 1965 to Bubicz ("*Bubicz*"), as well as the pending claims.

4. Essential bioactive components extracted from fruits or plant materials are well-known and widely used in the food industry. However, conventional techniques for extracting such bioactive components only extract some of the bioactive components from the fruit or plant material. For example, water extraction techniques, in which the bioactive components are extracted from insoluble fibers, preserve the natural image and nutritional functions of the bioactive components but are not very efficient. Solvent extraction techniques, while more efficient than water extraction, still fail to extract a substantial portion of the bioactive components from the fruit or plant material and simultaneously impair the nutritional functions of the bioactive components. Therefore, traditional water and solvent extraction techniques are only able to extract a few compounds of the fruit or plant material, leaving some other bioactive materials in the remaining material. For example, polysaccharides, polyphenols and other non-lipophilic compounds are not extracted together with the lipophilic components such as carotenoids, lipophilic vitamins and other lipids. See, Specification, page 1, line 23-page 2, line 28.

5. The present invention is directed, in part, toward improved compositions that include a primary composition retaining the important bioactive components of a fruit, vegetable or plant material. The profile of the bioactive component is close to that naturally occurring in the fruit, vegetable or plant material. Specifically, the essential bioactive components of the present claims are extracted from fruits, vegetable or plant materials by milling the material in a milk or milk protein-containing carrier. Milling the material contained in the milk or milk protein-containing carrier allows for the formation of much smaller particles of ground plant material, allowing more efficient access by the milk or milk protein-containing carrier to both the water-soluble and oil-soluble bioactives of the plant material. Milling in the presence of milk proteins also allows for the rupture of plant cells, which releases bioactive materials. Milk proteins are then able to interact with the insoluble (lipophilic) bioactive materials. The fruit or plant material is mixed in a milk or milk protein-containing medium and separated from

insoluble fibers to obtain an aqueous suspension. By using a milk or milk protein-containing carrier to extract the bioactive components from the fruit or plant material, the present claims provide bioactive components with improved miscibility, stability and bioavailability over conventional extraction techniques without the use of organic solvent residues. The present compositions, thus, are produced by processes that allow for the extraction of a greater amount of bioactive materials than with traditional water or solvent extraction techniques. See, specification, page 3, lines 19-page 4, line 10; page 7, lines 5-12.

6. *Pruthi* fails to disclose or suggest a primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable, and plant material, excluding insoluble fibers, and combinations thereof, with improved bioavailability, miscibility and stability as required, in part, by independent Claims 1, 12 and 14. *Pruthi* also fails to disclose or suggest to disclose or suggest a primary composition wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material by milling the material in the milk or milk protein-containing carrier as required, in part, by independent Claims 1, 12 and 14.

7. Instead, *Pruthi* is entirely directed toward a simple acqueous extraction of components of the Barberry plants. It is very clear that the milk of *Pruthi* is used in the same manner as the water during an aqueous extraction, and that Pruthi simply discloses a standard "infusion" process. Indeed, the boiling treatment discussed above in *Pruthi* is, as is commonly known in the art, applied for water-extraction. *Pruthi* also fails to even consider using milk proteins to extract lipophilic compounds. At no place in the disclosure does *Pruthi* even mention any milling or grinding process with respect to the Indian Barberry. Accordingly, *Pruthi* cannot disclose that the lipophilic bioactive components have the improved bioavailability, miscibility and stability of the compositions of the present invention that result from milling the fruit or plant material in a milk or milk protein-containing carrier as required, in part, by the present claims.

8. I have performed experimental tests comparing the compositions and methods of making same of the present invention to the compositions and methods of making same of *Pruthi*. Specifically, I prepared compositions according to the procedure described in column 3, lines 21-29 in *Pruthi*, as well as compositions according to Example 1 of the present specification. The extracts obtained from each composition clearly indicate that the quantity of zeaxanthin dipalmitates (ZP) (a key lipophilic bioactive material from wolfberry) extracted from 20 g of dried wolfberries is significantly higher in the extract obtained from Example 1 of the present specification (34.0 mg) when compared to the extract obtained from the process in *Pruthi* (4.0 mg).

9. To prepare the composition of *Pruthi*, I used wolfberry powder mixed with milk, boiled the mixture for 2 minutes, cooled the mixture to room temperature, filtered the mixture to remove leaves, dirt, and other particulate and then measured the extraction yield of ZP using spectrophotometer analysis. As discussed in the *Declaration*, the resulting extraction yield of ZP was 4.0 mg. The resulting extraction yield was light brown in color.

10. To prepare the compositions according to the present invention, I followed Example 1 of the specification. In the preparation, for example, I used dried wolfberry and milk to create a mixture. The mixture was wet-milled, decanted and then the extraction yield of ZP was measured using spectrophotometer analysis. As discussed in the *Declaration*, the resulting extraction yield of ZP was 34.0 mg. The resulting extraction yield was orange red in color. The orange red coloring of the composition prepared according to Example indicates a very different amount of carotenoids when compared to the extraction yield of *Pruthi*, which was light brown.

11. Therefore, upon experimental testing to compare *Pruthi* against the subject matter of the present claims, it is clear that *Pruthi* is simply an "infusion" process that uses mixing, boiling and filtering. *Pruthi* does not disclose or suggest that the plant cells should be ruptured in order to release the bioactive material and bring milk proteins into contact with insoluble (lipophilic) bioactives. In fact, it is quite evident from the quantity of ZP extracted from the composition of *Pruthi* and the color of the extract, that most of the bioactive material in the intact

plant cells cannot be extracted into the aqueous solution. This is in direct contrast to the present claims, which require that the bioactive component be wet-milled in milk, instead of simply mixing with milk, to extract bioactive materials. Accordingly, the process for obtaining the compositions, as well as the resulting compositions, are clearly different than the compositions disclosed in *Pruthi*.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: September 4, 2009

Print Name Junkuan WANG